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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,257	02/08/2002	Boyong Li	141-242A	9034

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
06/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,257	LI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 3/4/09.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Chen et al (USPN 6,270,805 hereafter '805) in view of Paradissis et al (USPN 5,133,974 hereafter '974). The claims are drawn to a once-a-day bupropion formulation comprising an immediate release portion, an enteric release portion and a sustained release portion.

The '805 patent discloses a multi-pellet controlled release formulation comprising an enteric coated pellet and a delayed release pellet comprising a water insoluble coating (abstract). The dosage form has a therapeutic plasma level in the range of 50 to 200 ng/ml (col. 1, lin. 15-19). The formulation is a once-a-day formulation comprising at least two pellets where the drugs

include bupropion hydrochloride (col. 3, lin. 4-6). The enteric coated polymers include pH dependent polymers such as methacrylic acid copolymers and Eudragit S or L (col. 3, lin. 30-40). The water-insoluble polymers coated to the delayed release pellets are selected from the Eudragit RS, ethyl cellulose, cellulose acetates and methacrylic acid ester (col. 4, lin. 15-30). The pellets comprise cores that are coated with the active agents and the polymers, specifically the water insoluble pellets are coated with an active layer and the water insoluble polymer (col. 4, lin. 5-15). The pellets are loaded into a unit dosage form such as a capsule for delivery (Example 1).

The reference is silent to an immediate release portion, however the inclusion of an uncoated immediate release portion is well known in the prior art as seen in the '974 patent. The '974 patent teaches a combination therapy comprising an immediate release portion of uncoated drug particles and a coated extended release portion comprising pellets (abstract). The extended release potion comprises coated pellets comprising a core where the coating comprising pH dependent polymers such as methacrylic acid copolymers (col. 7, lin. 3-10). The formulation can be formed into tablets, and filled into capsules (col. 7, lin. 30-40). It would have been obvious to combine the combined formulation with the pellets of the '805 patent since both patents teach similar extend release pellets and useful in providing a sustained release dosage form for up to 24 hours.

Regarding the in vivo plasma profile it is the position of the Examiner that such limitations would be inherent to any formulation meeting the structural limitations of the instant invention. Since plasma profiles are determined by the physical characteristics of a dosage form such as the polymer types, concentration and configuration, along with the types and concentration of the particular drugs, it is the position of the Examiner that any dosage from

meeting the physical limitations of the instant invention would also meet any in vivo plasma profiles claimed. The '805 patent teaches an extruded composition comprising a core which further comprises a carrier and at least one aminoketone antidepressant. The '805 patent further teaches the inclusion of each polymer claimed. Therefore it is the position of the Examiner that since each physical characteristic of the instantly claimed dosage from is met by the teachings of the '805 patent, the in vivo plasma profile is also met inherently.

Further the plasma profile would have been obvious to one of ordinary skill in the art. Since the general conditions of the claims have been met by the '805 patent, specifically the same polymers and drugs are used in an identical formulation, any manipulation of these parameters would be obvious to one of ordinary skill in the art. Likewise results falling from this manipulation would be obvious to one of ordinary skill in the art. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Further the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With these things in mind it would have been obvious to combine the combination therapy of the '974 patent into the '805 patent, providing an immediate release portion to the extended and sustained release pellets, in order to provide an improved pulsatile release over an extended period of time. It would have been obvious to combine these disclosures since the extended release polymers of each disclosure are identical and establish it is known to combine multiple release rates into one unit dosage form. One of ordinary skill in the art would have been motivated to combine these disclosures with an expected result of stable pulsatile dosage form.

Response to Arguments

Applicant's arguments with respect to claims 38-50 have been considered but are moot in view of the new ground(s) of rejection. However the Chen patent discloses multiple pellets comprising pH dependent coatings and water insoluble polymers coatings identical to the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618